

REMARKS

Claims 1-29 are currently pending in the application. Claim 29 has been allowed. Applicants appreciate that claims 16-18, 22 and 27-28 were indicated as being allowable if rewritten in independent form including all of the limitations of base and intervening claims. Claims 1 and 23 are also amended to correct antecedent basis of the "fluid." New claims 30-33 are added, which are supported by the specification and claims as filed. Applicants respectfully request reconsideration of claims 1-28, and allowance of all of the claims, i.e. claims 1-33.

1. Rejections under 35 USC § 102

On page 2 of the Office Action, claims 1-4, 6-7, 9-10, 14-15, 23, and 26 are rejected under 35 U.S.C. §102 (b) as being anticipated by Goldstein, et al. (U.S. Patent No. 5,899,937). Applicants respectfully traverse this rejection.

Anticipation requires the disclosure of each element of a claim under consideration in the cited reference. *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1987, (Fed. Cir. 1990) (en banc), *cert. denied*, 500 U.S. 904 (1991). It is not sufficient for the prior art to disclose the claimed elements in isolation. Rather, "[a]nticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (Citing *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

Applicants respectfully contend the Office Action does not make out a *prima facie* case of anticipation. The Goldstein reference fails to teach each and every claim element. Goldstein fails to teach the invention in as complete detail as is contained in

the claims. Further, Goldstein, et al. do not teach each and every claim element arranged as in the claims.

In the interest of brevity, Applicants incorporate by reference all previous arguments concerning Goldstein, et al. as if fully stated herein, and maintains that Goldstein, et al. has been improperly applied. It bears repeating, however, that Goldstein makes no disclosure, teaching or reference to a flexible membrane that does not fully open – Goldstein only teaches leaflets which are fully open. For example, it is stated that the leaflets are in a full open position along the sides of the nozzle (col. 7, lines 38-43), and the description of Fig. 2 clearly states that the "leaflets are shown in the fully open position". (col. 5, lines 2-3). Further, the text in Fig. 2 clearly states "fully open leaflets". Applicants respectfully submit it is evident that Applicants' flexible membrane is not analogous to Goldstein, et al.'s leaflet. Even assuming, arguendo, that the two structures were analogous, Goldstein, et al.'s disclosure of leaflets in a fully open position cannot anticipate the limitation that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23).

Applicants respectfully maintain that Goldstein, et al. do not teach every element of claims 1 and 23, and therefore fail to anticipate claims 1 and 23. Withdrawal of the stated rejection, and allowance of these claims are respectfully requested.

For reasons including the arguments made hereinabove, and those of record, claims 2-4, 6-7, 9-10, 14-15 and 26, which depend from independent claims 1 and 23, are also believed to patentably distinguish over the Goldstein reference. Applicants

reserve the right to present additional arguments in support of patentability of these claims, which recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-4, 6-7, 9-10, 14-15 and 26 are also in condition for allowance.

Applicants have added new claims 30-33 which depend from allowed claim 29, and are likewise patentable.

Applicants respectfully request withdrawal of the rejection of claims 1-4, 6-7, 9-10, 14-15, 23, and 26 under 35 U.S.C. §102 (a) as being anticipated by Goldstein, et al., and allowance of these claims. Applicants also request allowance of new claims 30-33 which also patentably distinguish over Goldstein, et al., either singly or in combination with the cited references.

2. Rejections under 35 USC § 103

a. Claims 5, 11-13, 19-21 and 25

Claims 5, 11-13, 19-21, and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldstein, et al. in view of Pietsch, et al. (U.S. Patent No. 4,778,461).

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations.

The disclosure of Goldstein, et al. is discussed above. Like Goldstein, et al., Pietsch, et al. do not teach leaflets less than fully open, so Pietsch, et al. do not remedy the deficiency in Goldstein, et al. The combination of Goldstein, et al. and Pietsch, et al. still only discloses leaflets that are in a fully open position. Since Goldstein, et al. in view of Pietsch, et al. contains absolutely no teaching or suggestion that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23), the independent claims and their dependent claims are not obvious.

Applicants believe the rejection of dependent claims 5, 11-13, 19-21 and 25, which depend from independent claims 1 and 23, are moot in view of the remarks made in connection with independent claims 1 and 23. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 5, 11-13, 19-21 and 25 are also in condition for allowance.

While Applicants reserve the right to present further arguments in support of patentability, Applicants note the following. The Office Action asserts that Pietsch, et al. disclose a heart valve stent with commissure posts and having a membrane of polyurethane or silicon integrally cast with the stent. However, Pietsch, et al. disclose a "support ring (or "stent")" (col. 3, line 1) that "supports only the lower part of the valve, whereas the upper part of the cusps and their joining zones (the commissures) remain free (col. 1, lines 66-68). Claims 5 and 19-21 include the feature of a stent comprising "a plurality of commissure posts, the flexible membrane extending between the commissure

posts." Pietsch, et al. do not disclose, and in fact, teach away from a heart valve stent with commissure posts, as the commissure posts referred to therein are not part of the "support ring (or "stent")" structure disclosed therein. The cited combination fails to meet the invention as claimed.

Applicants respectfully request withdrawal of the rejection of claims 5, 11-13, 19-21, and 25 under 35 U.S.C. § 103(a) as being anticipated by Goldstein, et al. in view of Pietsch, et al.

b. Claims 8 and 24

Claims 8 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldstein, et al. in view of Eberhardt (U.S. Patent No. 5,176,153).

In order to establish a *prima facie* case of obviousness, some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would support the combination must be shown. See, *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). A *prima facie* showing of obviousness has not been made. There is no suggestion to make the cited combination.

The Office Action asserts that Eberhardt discloses the use of certain test frequencies. However, Eberhardt does not teach leaflets less than fully open, so Eberhardt. does not remedy the deficiency in Goldstein, et al. Even if the combination of Goldstein, et al. and Eberhardt were proper, it still only discloses leaflets that are in a fully open position. Since Goldstein, et al. in view of Eberhardt contains no teaching or suggestion that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully

open in response to fluid pressure in a forward direction" (claim 23), the independent claims and their dependent claims are not obvious. The rejection must be withdrawn.

Applicants believe the rejection of claims 8 and 24 under 35 U.S.C. §103(a) as being obvious over Goldstein, et al. in view of Eberhardt is moot in view of the foregoing arguments made in connection with independent claims 1 and 23, in addition to Applicants' arguments of record removing the Goldstein reference. Dependent claims 8 and 24 include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 8 and 24 are also in condition for allowance.

Applicants have also added new claims 30-33 which are also believed to patentably distinguish over the cited combination.

Applicants respectfully request withdrawal of the rejection of claims 8 and 24 under 35 U.S.C. § 103(a) as being anticipated by Goldstein, et al. in view of Eberhardt.

3. Supplemental Comments

Applicants reiterate their position that the Office Action incorrectly asserted that Applicants define "does not fully open" as "opens no more than about 80% of the full open lumen at the inflow edge of the stent". While this is a limitation in some of the claims (claims 15, 26 and 29), it is not a limitation in claim 1 or any of the other claims.

4. Conclusion

In view of the foregoing amendments and arguments, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

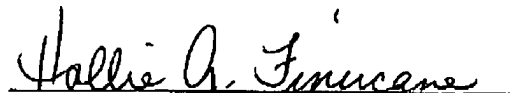
If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

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